

DISCUSSION OF THE CLAIMS

Claims 1-17 are pending in the present application. Claim 4 is presently withdrawn from active prosecution. Independent Claim 1 is amended to recite a composition that includes different calcium ion-supplying and monofluorophosphate ion-supplying compounds and to define the composition with respect to phosphate ion-supplying compounds. Support for the amendment is found in the examples and in paragraph [0009] on pages 4-5 of the specification. Claims 5-17 are new claims. Claim 5 is a new claim which recites a homogeneous composition having certain properties with respect to stability and storage. Support for new Claim 5 is found in the examples and in the original independent claims. Support for new Claims 6 and 7 is found in paragraph [0013] and [0017] of the PG publication corresponding with the present application (i.e., U.S. 2007/0128131). Support for new Claim 8 is found in the examples. Support for new Claim 9 is found in paragraphs [0019]-[0020] of the PG publication. Support for new Claims 10-11 is found in the examples. Support for new Claim 13 is found in paragraph [0016]. Support for new Claim 14 is found in paragraph [0019]. Support for new Claims 12 and 15-17 is found in the examples and as explained for the claims discussed above.

No new matter is believed to have been added by this amendment.

REMARKS

Applicants disclose and claim a composition that may be used for dental care and/or that has substantially improved stability in comparison to conventional dental care compositions.

The composition of amended Claim 1 includes different calcium ion-supplying and monofluorophosphate ion-supplying compounds and substantially excludes phosphate ion-supplying compounds.

The composition of new Claim 5 must meet one of the conditions (i) and (ii) explicitly recited in the claim. The property (i) is especially relevant to mouthwash compositions which must remain transparent and not settle or precipitate (Applicants draw the Office's attention to new Claim 15 which recites a homogeneous *solution* that meets the condition relevant to a mouthwash). Property (ii) of Claim 5 is particularly relevant to paste and gel compositions which must maintain the ability to provide fluorine-containing calcium ions to tooth surfaces.

The compositions of Claims 1 and 5 include both a monofluorophosphate and calcium ion sources in a single stable homogeneous composition. The calcium ion-supplying compound and the monofluorophosphate ion-supplying compound of Claims 1 and 5 must be different.

Conventional compositions which contain both monofluorophosphate and calcium ion sources tend to precipitate calcium fluoride and/or are otherwise non-homogeneous. This has two substantially detrimental effects; namely, (i) the particle size of the composition begins to increase and (ii) the calcium fluoride precipitation product cannot be absorbed into teeth thus rendering the composition ineffective for dental care. Applicants have disclosed and claimed a homogeneous composition (e.g., single part composition) which includes both a

homogeneous monofluorophosphate ion-supplying compound and a calcium ion-supplying compound that does not suffer the disadvantages of conventional compositions.

The examples of the specification demonstrate the substantially superior stability of the claimed composition. Table 1 compares two inventive examples with a comparative example. The comparative example is like the inventive example but does not include the acid component recited in the present claims and is unable to meet the pH requirement recited in the present claims. Table 1 describes mouthwash compositions in terms of their stability and storage. The inventive examples avoid the precipitation of calcium fluoride materials as is evident by the “residual factor of monofluorophosphate ions” which ranges from 87-99% for Inventive Examples 1 and 2. Comparative Example 1 provides a residual factor of monofluorophosphate ions of only 30% (see table 1 below).

TABLE 1

		Example 1	Example 2	Compar- ative Example 1
Composition	Calcium glycerophosphate	1	1	1
	Sodium monofluoro-phosphate	0.7	0.7	0.7
	Lactic acid	0.6	2	
	Sodium hydroxide (pH regulator)		0.91	
	Purified water	Balance	Balance	Balance
	Total	100	100	100
pH immediately after formulation		5	5	8
Usability (Astringency)		1.6	1.5	1.5
Stability in storage	Changes in appearance	2	2	0
	Residual factor of monofluorophosphate ions	87%	99%	30%
	Residual factor of calcium ions	88%	94%	32%

Inventive Examples 3-7 describe toothpastes. The compositions of Inventive Examples 3-7 and their performance properties are described in Table 2. The inventive

examples are substantially more stable with respect to residual factor of calcium ions in comparison to Comparative Example 3. It should be noted that Comparative Example 2 has a high residual factor of calcium ions but a very low usability as reflected in an unpleasant astringent flavor.

TABLE 2

	Composition	Example					Comparative Example	
		3	4	5	6	7	2	3
Calcium Glycerophosphate	1	0.6	0.6		0.6	0.6	0.6	0.6
Calcium Lactate		0.6	0.6	1.5	0.6	0.6	0.6	0.6
Sodium Monofluorophosphate	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Lactic Acid	2	2	0.2	2		2		
Malic Acid					0.17			
Sodium Hydroxide (pH Regulator)	1.2	0.36		0.9				
Sorbit Solution (70% by weight)	40	40	40	40	40	40	40	40
Xylitol	6	6	6	6	6	6	6	6
Silicic Anhydride	15	15	15	15	15	15	15	15
Sodium Saccharin	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sodium lauryl sulfate	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Sodium Carboxymethylcellulose	1	1	1	1	1	1	1	1
Carageenan	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Xanthan Gum	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Polyethylene Glycol 600	4	4	4	4	4	4	4	4
Flavorant (Peppermint)	1	1	1	1	1	1	1	1
Purified Water	Balance	Balance	Balance	Balance	Balance	Balance	Balance	Balance
Total	100	100	100	100	100	100	100	100
pH (Aqueous Solution of 10% by Weight)	6	4	6	5	6	3.5	7.5	
Stability Changes from Discoloration in Storage	2	2	2	2	2	0	2	
Residual Factor of Calcium Ions* ¹	99%	99%	97%	99%	97%	99%	55%	
Residual Factor of Calcium Ions* ²	—	95%	76%	—	80%	99%	39%	
Usability (Astringency)	1.8	1.2	1.9	1.9	1.9	0.3	1.9	

*¹4 days

*²1 month

Applicants have thus shown that the presently claimed invention is substantially superior to conventional dental care compositions which suffer from calcium fluoride precipitation and/or loss of dental protection efficacy.

The Office cited Lee (U.S. 6,214,321) against the original claims, alone or in combination with either of Abbate (U.S. 6,372,198) or Winston (U.S. 6,036,944). The Lee composition is substantially different from the composition of the present claims. This difference is recognized by the Office in paragraph no. 3 on pages 3-4 of the November 24, 2009 Office Action. In particular, Lee discloses an oral product that is used by combining two distinct and separate portions. The first portion of the Lee oral product is one that includes a calcium phosphate. The second Lee portion is one that includes a

monofluorophosphate. The oral product of the Lee patent separates the calcium and fluorophosphate components for the reason that storing such materials together results in the undesirable precipitation of a calcium fluoride and/or other material thereby decreasing the efficacy of the Lee oral product (see for example, col. 2, lines 34-44).

Lee does not disclose or suggest a homogenous composition comprising each of components (A), (B) and (C) recited in the present claims. In fact, Lee separates a calcium-containing component and a monofluorophosphate-containing component to avoid undesirable precipitation.

Irrespective of the observations above, the compositions of Lee include a phosphate ion-supplying compound (i.e., a calcium phosphate salt) that is substantially excluded from the composition of Claim 1. Applicants thus submit that the subject matter of present Claim 1 is novel and not obvious over the Lee patent and respectfully request withdrawal of the rejection.

With regard to new Claim 5, Applicants submit that those of ordinary skill in the art would not be led to the presently claimed invention from the Lee disclosure. Those of skill in the art would, instead, be led to believe that combining a calcium source and a monofluorophosphate source in a single composition would necessarily result in the precipitation of a material such as calcium fluoride and that such a combination would deactivate a homogeneous composition. In effect those of skill in the art would not be led to believe that a homogeneous composition could exhibit the stability required by new Claim 5.

The Office alternately rejected the claims by combining Lee with Abbate or Winston. Like Lee, Winston teaches away from the combination of both a monofluorophosphate ion-supplying compound and a calcium ion-supplying compound in a single homogeneous composition. Winston explicitly discloses that such compositions are subject to the potential loss of fluoride (see col. 9, lines 7-18 of Winston).

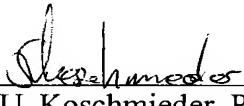
Abbate, like Lee, discloses the use of multiple portions that are mixed prior to application to a tooth surface (see the Abstract of Abbate). The references together do not suggest the presently claimed invention which require certain stability properties in a homogeneous composition.

Applicants thank Examiner Maewall and SPE Kishore for the helpful and courteous discussion of February 1, 2010. During the discussion Applicants' U.S. representative argued that the compositions of the cited art suffer from precipitation and settling that disrupts their effectiveness.

For the reasons discussed above, Applicants request the withdrawal of the rejection and the allowance of all now-pending claims.

Respectfully submitted,

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